

M E M O R A N D U M D E P A R T M E N T O F H E A L T H A N D H U M A N S E R V I C E S
P U B L I C H E A L T H S E R V I C E
F O O D A N D D R U G A D M I N I S T R A T I O N
C E N T E R F O R D R U G E V A L U A T I O N A N D R E S E A R C H

DATE: July 24, 2002

FROM: Eric Duffy, Ph.D.
Director, DNDCII, ONDC

SUBJECT: Approval of NDA 21-402
Synthroid® (levothyroxine sodium tablets, USP)
Abbott Laboratories

TO: Citizen Petition – 02P-0135/PSA1
NDA 21-402 File

Jerome Stevens Pharmaceuticals, Inc. (Jerome) submitted a Petition for a Stay of Action, No. 02P-0135/PSA1, dated March 26, 2002, and filed by the Agency on March 28, 2002. The petition requests that FDA stay (1) all grants of drug pre-market authority that were based on New Drug Applications (NDAs) or Abbreviated New Drug Applications (ANDAs) that used, relied on, or were based on Jerome's confidential and trade secret manufacturing information for orally-administered levothyroxine sodium (LS) and (2) all pending and prospective NDAs and ANDAs that use, rely on, or are based on Jerome's confidential and trade secret manufacturing information for orally administered LS. Jerome claimed in a Notice of Claims Pursuant to the Federal Tort Claims Act dated March 26, 2002 (Notice) that certain information that had been posted on FDA's Website (<http://www.fda.gov/cder/>) on August 22, 2000, regarding Jerome's NDA for LS was confidential and trade secret information.

The Office of New Drug Chemistry has reviewed Abbott Laboratories (Abbott's) NDA 21-402, submitted on July 31st, 2001 and has determined that the Abbott NDA did not use or rely on, and was not based on Jerome's allegedly confidential information. This determination is based on the fact that the batches Abbott used to support its NDA 21-402 were manufactured using a different formulation and method of manufacture than those utilized by Jerome.¹ In addition, the formulation and method of manufacture for Abbott's drug product, as provided in Abbott's NDA, are unchanged from those utilized for the pre-NDA product, with the exception of the deletion of an overage of active ingredient. The pre-NDA drug product formulation and manufacturing method dates back to the mid-1990's.

¹ The filing of this memorandum solely represents a determination that the Abbott NDA did not use or rely on, and was not based on Jerome's allegedly confidential information. It does not represent a determination with regard to any other issue, nor does it constitute an admission of any issue raised by Jerome's Petition or Notice.